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No. 06-1582

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IN THE

Supreme Court of the United States

PFIZER, INC.,

Petitioner,

v.

APOTEX, INC. (F/K/A TORPHARM, INC.),

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF IN OPPOSITION

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PARTIES TO THE PROCEEDINGS

All parties to the proceeding are identified in the caption.

CORPORATE DISCLOSURE STATEMENT

Apotex Pharmaceutical Holdings, Inc. is the parent of Apotex, Inc. There are no publicly held companies that own 10% or more of the corporation's stock.

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BRIEF IN OPPOSITION

STATEMENT

Petitioner Pfizer, Inc. filed suit against respondent Apotex, Inc., alleging that Apotex's application for approval to market a generic version of Pfizer's amlodipine besylate drug product, which Pfizer markets under the trademark Norvasc® for treating hypertension and angina, infringed U.S. Patent No. 4,879,303 ("the '303 patent"). Pet. App. 1a. The '303 patent was Pfizer's second patent covering its popular Norvasc® heart medication. Pfizer held market exclusivity for Norvasc® for many years based on U.S. Patent No. 4,572,909 ("the '909 patent"), issued on February 25, 1982, that also covered Norvasc®. Pet. App. 3a-4a.[1] Apotex denied infringement

[1] In fact, Pfizer applied for and received a 1,252 day patent term extension for the '909 patent specifically based on the time it took the FDA to

and contested the validity of the patent on grounds of obviousness. Pet. App. 2a. After a bench trial, the district court entered judgment for Pfizer and enjoined Apotex from marketing its generic until September 25, 2007. Pet. App. 2a. Although the '303 patent expired on March 25, 2007, Pfizer received an additional six month period of marketing exclusivity during which time the FDA would forego granting final approval to generic competitors as a result of its agreement to conduct tests to determine the efficacy of amlodipine besylate in children, if Pfizer met certain statutory requirements. Pet. 5-6, 16.

On March 22, 2007, the court of appeals reversed, concluding that the '303 patent was invalid for obviousness. Pet. App. 38a. As the court noted, "a claimed invention is unpatentable if the differences between it and prior art 'are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.'" Pet. App. 18a (quoting 35 U.S.C. § 103(a)). In this case, the active ingredient identified in the '909 patent, amlodipine, is the same as the active ingredient in the '303 patent. The '909 patent also claimed all pharmaceutically acceptable acid salts of amlodipine, of which besylate is one. Pet. App. 4a-5a; 18a. The '909 patent noted that the preferred salt form was the maleate. Pet. App. 4a-5a. However, Pfizer had difficulty producing amlodipine maleate in commercial tablet forms. Pet. App. 4a-5a. Standard laboratory practices eventually determined that besylate salt would be preferable for marketing a tablet, and although its initial efforts to obtain a patent for amlodipine besylate were rejected by the Patent Office as obvious, eventually Pfizer obtained the '303 patent. Pet. App. 6a-9a, 29a-30a. The court of appeals found that there was clear and convincing evidence that "one skilled in

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approve Pfizer's Norvasc® (amlodipine besylate) product, which is expressly claimed in the '303 patent as well. *See Pfizer, Inc. v. Dr. Reddy's Labs.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004).

the art would have been motivated to combine the teachings of the '909 patent, Berge [a leading scholarly article in the field], and other prior art, to produce the besylate salt of amlodipine." Pet. App. 23a. The evidence also showed that there was a reasonable expectation of success when using besylate as an addition salt. Pet. App. 23a-26a. After rejecting Pfizer's claim that the evidence showed no more than it would have been obvious to try amlodipine besylate (Pet. App. 26a-32a), and after finding that Pfizer failed to prove any secondary considerations sufficient to overcome the strong showing of obviousness (Pet. App. 32a-37a), the court of appeals held the '303 patent invalid and unenforceable. Pet. App. 38a.

On May 21, the court of appeals denied Pfizer's petition for rehearing and rehearing en banc and granted Apotex's motion for immediate issuance of the mandate. Pet. App. 39a-40a. On May 30, Pfizer filed a petition for certiorari along with motions to recall and stay the mandate of the court of appeals and to expedite consideration of the petition for certiorari. On June 6, Justice Stevens denied the motion to recall and stay the mandate, and on June 11, the court denied the motion to expedite. On June 14, Pfizer filed a letter with the FDA seeking to have the '303 patent delisted from the FDA's Approved Drug Products List with Therapeutic Evaluations Equivalents on the ground that the '303 patent could no longer be asserted against any entity marketing a generic equivalent of amlodipine besylate. Supp. Br. 1.

ARGUMENT

Pfizer does not seek plenary review. Instead, it seeks vacatur of the judgment of the court of appeals and a remand directing that court to reconsider this case in light of this Court's decision in *KSR Int'l Corp. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). In fact, the court of appeals has already considered *KSR* as it ruled on Pfizer's petition for rehearing; a remand for reconsideration would therefore be pointless.

Moreover, there is no tension between the decision below and *KSR*; if anything, this Court's holding in *KSR* suggests that the Federal Circuit has unduly circumscribed the defense of obviousness, and any error on that score would inure to Pfizer's benefit. Moreover, in this case and in its other recent decisions, the Federal Circuit has adopted an approach to obviousness that anticipated the holding in *KSR*. Just as the Court recently denied a petition for certiorari in another case from the Federal Circuit taking the same approach as the decision below, the Court should deny certiorari here.

Pfizer also argues that if this Court does not rule on its petition for certiorari until after the period of pediatric exclusivity expires on September 25, 2007, it should vacate the judgment of the court of appeals as moot. In fact, it is far from clear that this case will be moot after September 25; it is only Pfizer's tactical decision to abstain from seeking the remedies that may be available at that point that supports its claim for mootness. A party is not, however, entitled to vacatur of an unfavorable judgment on grounds of mootness merely as a consequence of its litigation tactics.

1. Pfizer does not claim that this case merits plenary review. Indeed, Pfizer's petition presents only two questions – the first requests summarily vacating the judgment of the court of appeals and remanding for further consideration in light of *KSR*, and the second seeks vacatur of the judgment of the court of appeals as moot if the petition is not granted prior to September 25, 2007. *See* Pet. i. Under its rules, this Court will consider only the questions set out in a petition for certiorari. *See* Sup. Ct. R. 14.1(a). Thus, while Pfizer claims that the decision below is out of step with *KSR* and will call into question the validity of many patents (Pet. 8, 14-15), it apparently recognizes that this assertion does not support plenary review. The Federal Circuit will have many opportunities to assess the consistency of the holding below with *KSR*. Moreover, if, in the future, this Court perceives that the

Federal Circuit is unwilling or unable to hew to the holding in *KSR*, it will have ample opportunity to provide correction.

2. Instead of plenary review, Pfizer seeks summary vacatur of the judgment of the court of appeals and a remand directing that court to reconsider the case in light of its *KSR* decision. *See* Pet. 9. The court of appeals, however, has already considered *KSR* as it ruled on Pfizer's petition for rehearing and rehearing en banc; and not a single member of that court thought that anything in *KSR* warranted any alteration in its judgment in this case.

Nearly a month before the court of appeals denied its petition for rehearing, Pfizer brought *KSR* to the attention of that court of appeals in support of its petition for rehearing, as Pfizer acknowledges. See Pet. 6. Apotex's motion to issue the mandate, filed while the petition for rehearing remained pending, also brought this Court's decision in *KSR* to the attention of the court of appeals, and Pfizer again addressed *KSR* in its response to that motion. See Opposition to Motion to Stay and Recall Mandate Exhs. A & B (No. 06A1131). Even aside from the parties' filings in the court of appeals, it would be absurd to believe that the judges of the Federal Circuit would not have bothered to read a decision of this Court dealing with subject matter of intense concern to that specialized court.[2] In any event, the court of appeals denied Pfizer's petition for rehearing and issued its mandate immediately, and of the twelve judges who acted on the petition for rehearing en banc, only three voted to grant it, despite Pfizer's claim that KSR supported its position. See Pet. App.

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[2] Indeed, the Federal Court had already evinced its awareness that this Court had granted plenary review in *KSR* even before this Court's opinion came down. *See DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 n.3 (Fed. Cir. 2006) ("Indeed, the United States Supreme Court recently granted certiorari in a case involving this court's application of the suggestion test."), *cert. denied*, 75 U.S.L.W. 3661 (U.S. June 11, 2007) (No. 06-1207).

39a-40a. Perhaps of even greater importance, none of the three judges who voted to grant rehearing accused the panel's holding of reflecting any inconsistency with *KSR*. *KSR* appeared in one of the dissenting opinions only to support the proposition that "[c]hemical and pharmaceutical compounds often can be found to be prima facie obvious, as they are based on prior work that could reasonably suggest them." Pet. App. 49a (Lourie, J., dissenting).

In short, it is plain that the court of appeals was fully aware of *KSR* as it denied Pfizer's petition for rehearing. A remand for reconsideration would impose a pointless burden on the court of appeals.

3. The court of appeals was quite right to conclude that there was no tension between the holding below and this Court's decision in *KSR*. Although Pfizer claims that the court of appeals erred by applying a version of its teaching, motivation, suggestion test ("TSM") in invalidating the asserted claims of Pfizer's patent, *see* Pet.12-14, that claim will not bear scrutiny.

At the outset, Pfizer does not argue that under *KSR*, it is impermissible to assess these factors in undertaking an obviousness inquiry. To the contrary, *KSR* is quite clear that the TSM test is consistent with the leading case on the defense of obviousness, *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), so long as the TSM inquiry is not used to unduly circumscribe the defense:

> Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility. In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea under-

> lying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

KSR, 127 S.Ct. at 1741. In *KSR*, the Court simply rejected the Federal Circuit's use of an overly rigid application of the TSM test that left the obviousness defense unduly circumscribed.

> The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under *§ 103*. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

Id. at 1742.

Thus, *KSR* broadened the defense of obviousness in comparison to the test that the Federal Circuit had employed in that case. For that reason, Pfizer's reliance on *KSR* is more than a little anomalous. In *KSR*, this Court held that a sensor for a position-adjustable vehicle pedal assembly was invalid on grounds of obviousness, overturning the approach taken by the Federal Circuit, which had improperly limited that defense. *See* 127 S. Ct. at 1739-46. There is no reason to believe that a second look at *KSR* would convince the court of appeals to uphold Pfizer's patent when it had already invalidated that patent on grounds of obviousness. If anything, it is the dissenting opinions below, on which Pfizer bases its request for this petition that appear out of step with *KSR*. *Compare KSR*, 127 S. Ct. at 1742 ("The same constricted

analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try.'") with Pet. App. 41a (Newman, dissenting) ("The panel's application of the obvious-to-try standard is in direct conflict with precedent . . . . '[W]e have consistently held that 'obvious to try' is not to be equated with obviousness.'" (quoting *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990)).

Indeed, rather than reflecting inconsistency with *KSR*, the decision below anticipated its holding by adopting a flexible conception of obviousness:

> [A] suggestion, teaching, or motivation to combine the relevant prior art teachings to achieve the claimed invention does not have to be found explicitly in the prior art references sought to be combined, but rather "may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." In other words, it is irrelevant that none of the anions specifically listed in the '909 patent have a cyclic structure, because the motivation to make amlodipine besylate here is gleaned not only from the prior art as a whole rather than the '909 patent alone, but also from the nature of the problems encountered with the amlodipine maleate tablet formulations sought to be solved by the inventors of the '303 patent.

Pet. App. 19a-20a (citations omitted) (quoting *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006), *cert. denied*, 75 U.S.L.W. 3661 (U.S. June 11, 2007) (No. 06-1207)).

Pfizer also notes that the Court in *KSR* "reaffirmed the notion that where combinations yield unexpected results, the unexpected nature of the results cuts against a finding of obviousness." Pet. at 13. But in the decision below, the Federal Circuit expressly recognized that unexpected results may overcome a showing of prima facie obviousness. Pet.

App. 33a ("Evidence of unexpected results can be used to rebut a prima facie case of obviousness."). It then devoted several pages of its decision to explaining why the results touted in Pfizer's patent were not unexpected at all in view of the prior art before concluding: "Pfizer has simply failed to prove that the results are unexpected." Pet. App. 36a.

Accordingly, there is no tension between the decision below and *KSR*. To the contrary, in *KSR*, this Court characterized the case on which the court of appeals primarily relied below, *DyStar* (Pet. App. 18a, 20a, 27a, 31a), as "elaborat[ing] a broader conception of the TSM test than was applied in the instant matter," and added that the approach taken in *DyStar* was "not now before us . . . ." 127 S. Ct. at 1743. Thus, there is no inconsistency between *DyStar* and *KSR*, as this Court has already recognized. Just weeks ago, the Court denied a petition for certiorari in *DyStar*, rather than vacating and remanding for reconsideration in light of the intervening decision in *KSR*. *See DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 75 U.S.L.W. 3661 (U.S. June 11, 2007) (No. 06-1207). There is no more reason to vacate and remand in this case.

Thus, nothing in *KSR* warrants vacatur of the judgment of the court of appeals and a remand for reconsideration. The decision below was based on *DyStar* and not the approach that this Court rejected in *KSR*. It is presumably for that reason that even the dissenting judges below saw nothing in *KSR* that supported their view on the validity of the '303 patent.

4. Pfizer argues that after the expiration of the statutory period of pediatric exclusivity on September 25, 2007, the judgment of the court of appeals should be vacated as moot because Pfizer's rights flowing from the patent will have expired. *See* Pet. 16-19. It is, however, far from clear that this case will be moot after September 25.

Under the statutory pediatric exclusivity provision, a patented drug already gains an additional six months of exclusivity for a patent holder that undertakes pediatric testing of the drug at the FDA's request. *See* 21 U.S.C. § 355a(c)(2). Thus, "[u]nder the statute . . . the patent holder is eligible to receive a six-month period of market exclusivity for the drug beyond the patent expiration date." *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1276 (D.C. Cir. 2004). In this case, however, were Pfizer to eventually sustain the '303 patent on the merits, it would have been deprived of its rights to six months of pediatric exclusivity as a result of an erroneous judicial decision invalidating that patent. Although Pfizer now disclaims any ability to obtain a decision on the merits after September 25, it is far from clear that the statute offers Pfizer no remedy for such a deprivation of statutory rights, should it ultimately prevail in this action.

In *Astrazenica AB v. Impax Laboratories, Inc.*, No. 00 CIV. 7597(BSJ), 01 CIV. 2998(BSJ), M-21-81 (BSJ), MDL 1291, 2007 WL 1612053 (S.D.N.Y. May 25, 2007), for example, the court held that the expiration of the original rights under a patent coupled with the FDA's approval of generic equivalents for marketing did not moot an infringement action brought during the period of pediatric exclusivity, reasoning: "The Court agrees that the six-month period of pediatric exclusivity does not extend the term of the patents, but it does grant the patent holder a period of market exclusivity, which this Court has the power to enforce." *Id.* at *7. As the decision in *Astrazenica* suggests, it is far from clear that Pfizer will have no remedy after September 25 if it ultimately prevails in this action and establishes that the judgment of the court of appeals wrongfully cut short its period of statutory exclusivity. If it were to uphold the patent on remand from this Court, perhaps the court of appeals would then conclude that the district court has the power to enjoin Apotex and perhaps even others from further marketing of its generic equivalent for an additional period of time until Pfizer

has received a full six-months of exclusivity. Or, perhaps the court will conclude that Pfizer is entitled to seek damages from Apotex.

To be sure, nothing in the applicable statute expressly grants a patentee a right of action against competitors if it believes it has been wrongly deprived of its right to six months of statutory exclusivity. Still, an implied right of action could be derived from the statute. Traditionally, this Court has looked to four factors in endeavoring to determine whether an individual right of action can be implied from a statute – whether the plaintiff is a member of a class for whose special benefit the statute was enacted; whether there is any indication of a legislative intent to grant or deny such a remedy; whether it is consistent with the underlying purposes of the statute to imply a remedy; and whether the subject matter at issue is traditionally governed by state law. *E.g.*, *Cort v. Ash*, 422 U.S. 66, 78 (1975). The Court has more recently stressed that the statute must manifest an intent to create enforceable private rights for a private right of action to be implied. *See, e.g.*, *Gonzaga University v. Doe*, 536 U.S. 273, 283-84 (2002). It is certainly far from clear how this inquiry should be resolved in this case. Perhaps the statute should be read as merely a directive to the FDA; indeed, it is clear that Congress intended many aspects of the Food and Drug Act to be policed exclusively by the FDA. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348-52 (2001). Nevertheless, in light of the manifest statutory intent to provide patentees with assurances of exclusivity should they agree to the FDA's requests for pediatric studies, coupled with Congress's understandable failure to anticipate a situation in which an erroneous judicial decision cuts short the period of exclusivity, the requisite intent to create a private remedy could well be present.

In any event, even if no private right of action to enforce the statutory right of exclusivity can be implied, perhaps the

FDA would itself take action to grant Pfizer an additional period of exclusivity should it ultimately prevail in this case. In *Mylan Laboratories*, for example, the FDA revoked its order approving the marketing of a generic drug following a district court's decision upholding the patent on that drug and enforcing the patentee's right of pediatric exclusivity. *See* 389 F.3d at 1277-78. The court upheld this action as a reasonable effort to administer an ambiguous statute. *See id.* at 1281-84. As the decision in *Mylan* suggests, the FDA takes the right to pediatric exclusivity seriously, and its efforts to protect those rights will receive deference on judicial review. Were Pfizer to ultimately prevail in this case, the FDA might itself choose to revoke the right of generic competitors to market their drugs for a period of time in order to grant Pfizer a full six months of exclusivity.

To be sure, the answer to the question whether Pfizer might have some remedy after September 25 should the judgment of court of appeals be vacated is unclear; we have no confidence in the outcome of that inquiry, and we certainly intend to concede nothing through the instant submission. What is clear, however, is that the party asserting mootness has the burden of establishing that the parties no longer have any meaningful stake in the outcome of the litigation. *See, e.g., Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 98 (1993). It is equally clear that a party cannot obtain vacatur of an unfavorable judgment as moot because of its voluntary litigating decisions; indeed, the Court has written that "[t]he principal condition to which we have looked is whether the party seeking relief from the judgment below caused the mootness by voluntary action." *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 24 (1994). Thus, Pfizer's tactical decision not to press any right it might have to seek either a judicial or administrative remedy after

September 25 surely cannot entitle it to vacatur of the judgment below.[3]

What is more, vacatur is an equitable remedy, and "[i]t is petitioner's burden, as the party seeking relief from the status quo of the appellate judgment, to demonstrate . . . equitable entitlement to the extraordinary remedy of vacatur." *U.S. Bancorp.*, 513 U.S. at 26. Pfizer's case on the equities, however, is particularly weak. Not only has it already enjoyed the full period of patent protection for the '303 patent as well as a portion of the period of pediatric exclusivity, but its petition makes no effort to consider the potential for a judicial or administrative remedy after September 25. Surely it is the burden of those who seek equitable relief to make a proper and detailed showing that they have no other remedy available. *See, e.g., FCC v. Radiophone, Inc.*, 516 U.S. 1301, 1301 (1995) (Stevens, J., in chambers) ("I am persuaded, however, that allowing the national auction to go forward will not defeat the power of the Court of Appeals to grant appropriate relief in the event that respondent . . . prevails on the merits."). That showing is entirely absent in the petition. Perhaps it will come in the reply brief, when we will have no opportunity to respond, but that is doubtless too late for equity to countenance.

Indeed, the equitable case for vacatur is especially weak since the petition is without substance. As we explain above, there is no basis here for either plenary review or a remand for reconsideration. The right to press a petition for certiorari that Pfizer claims it is losing due to the passage of time is accordingly worthless; there is nothing remotely certworthy about this case. Pfizer should not be able to obtain vacatur of

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[3] For this same reason, Pfizer's decision to voluntarily delist the '303 patent cannot entitle it to vacatur on grounds of mootness. Indeed, Pfizer acknowledges that "the delisting letter does not moot this case." Supp. Br. 2.

an unfavorable precedent merely because events may have overtaken an otherwise worthless petition for certiorari. Just as Justice Stevens found nothing about this case that warranted the equitable relief of a recall and stay of the mandate, nothing in the petition supports the equitable relief of vacatur.

CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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